# Exhibit A

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF WEST VIRGINIA**
**AT CHARLESTON**

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| **IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**THIS DOCUMENT RELATES TO WAVE 1 / TVT-R CASES** | **Master File No. 2:12-MD-02327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

# RULE 26 EXPERT REPORT OF ANNE HOLLAND WILSON, MBA

## I. QUALIFICATIONS

As a Biomedical Engineer and Quality Assurance Consultant, I focus exclusively on medical devices. My work experience includes extensive experience with permanently implantable devices, as well as reusable devices and disposable devices. My areas of expertise include risk management for medical devices, as well as design controls, quality system development, auditing, and manufacturing process optimization.

I received a Bachelor of Science in Biomedical Engineering from Vanderbilt University in 1985, and a Master of Business Administration from the University of Colorado in 1991.

I currently hold certifications as a Certified Quality Auditor, Certified Quality Engineer, and Certified Quality Manager through the American Society for Quality, a Quality System Lead Auditor through Exemplar and as a Registered Quality Assurance Professional in Good Laboratory Practice through the Society of Quality Assurance. I am a Senior Member and served as Chair of the Austin Section of the American Society for Quality in 2004-2005. In addition to the American Society for Quality, I am a member of the American Society for the Advancement of Medical Instrumentation, Regulatory Affairs Professional Society, and the Society of Quality Assurance. I have also guest lectured at universities and industry seminars on topics such as design controls, risk management and process validation for medical devices.

In 2000, I founded QA Consulting, Inc. where I continue to serve as CEO. I consult with medical device manufacturers to develop and implement compliant solutions for their quality practices. I have completed 100+ supply chain/internal audits to U.S and International Standards. While the 510(k) process is not part of this report, I have been involved in over 30 510(k) applications and am familiar with the requirements relating to FDA clearance of a medical device. The process described herein is not part of the 510(k) process, but instead relates to the industry standards that medical device companies must follow in designing a safe device for the lifetime of that product.

Prior to creating my company, I worked as a Senior Manufacturing Engineer, QA Manager, and Senior Quality Assurance Engineer over the course of 6 years with Sulzer Carbomedics of Austin, TX. Prior to those positions, I served as Project Manager and Design Assurance Engineer with Ohmeda Monitoring, Quality Assurance Project Engineer with Cobe BCT, Inc., Quality Assurance Engineer with Fischer Imaging Corporation, and Project Engineer with LA BAC Medical Systems.

My 30 years of experience as a Biomedical Engineer in quality assurance, ranging from design concept and research and development through manufacturing/production and post-market surveillance for Class I, II, and III medical devices has afforded me expert knowledge of medical device industry regulations and standards, including but not limited to Title 21 – Food and Drugs of the Code of Federal Regulations, particularly Section 820, Quality System Regulation, and Section 58, Good Laboratory Practice for Nonclinical Laboratory Studies, as well as ISO Standards 13485, Medical Devices - Quality management systems – Requirements for regulatory purposes, 14971, Medical Devices – Application of risk management to medical devices, and 9001, Quality management systems – Requirements.

My experience, education, and certifications along with a complete list of my publications and presentations are outlined in my Curriculum Vitae attached to this report as Exhibit 1.

## II. BACKGROUND

I have been asked to address the design control and risk management processes of Ethicon, Inc., Ethicon Women's Heath and Urology, a Division of Ethicon, Inc., Gynecare, and Johnson & Johnson (collectively referred to as Ethicon) associated with the manufacture of the GYNECARE Tension Free Vaginal Tape (TVT-R) System which is a medical device indicated for treatment of stress urinary incontinence (SUI). The TVT-R device is a kit which contains several components designed to be used as a system, including: [1]

1. PROLENE® polypropylene mesh; the mesh is available in both mechanical cut ("MCM") since its introduction to the United States and laser cut mesh ("LCM") which became available in 2006. The mesh, whether MCM or LCM, always came with a polyethylene sheath or covering and attached needles (sold sterile)
2. A TVT introducer (reusable sold non-sterile)
3. A TVT Rigid Catheter Guide (reusable sold non-sterile)
4. Instructions for use (IFU)

All of my opinions expressed in this Report are offered to a reasonable degree of professional certainty within my field.

In the course of my work on this case, I analyzed, reviewed, and relied upon the following categories of information, listings of which are provided in Exhibit 3: (a) applicable, standards, and guidance documents; (b) Ethicon documents, including, but not limited to risk management documents and quality assurance documents; and (c) deposition transcripts of Ethicon employees.

[1] Eth.Mesh.01317508.

In my profession as a Biomedical Engineer and Quality Assurance Consultant for medical device companies, I routinely analyze medical device manufacturers' risk management processes and identify their strengths and weaknesses. I regularly look at medical device companies' design and risk management documents, including design history files and FMEAs, and evaluate whether that documentation complies with industry standards and practices. For example, I routinely use root cause analysis methodologies to identify the deficiencies in medical device companies' processes such as design control, risk management, production issues, or CAPAs. These are the same analysis methods that I have performed in the course of my work in this case.

## III. SUMMARY OF OPINIONS

A summary of the opinions presented herein is below:

1. The TVT-R was developed in Europe and sold to Ethicon by a company called Medscand. Ethicon introduced the product to the United States in 1998. I reviewed the initial design documents prepared by Medscand and Ethicon in connection with my work in this case. Ethicon's design documentation for the TVT-R, as outlined in the Design History File (DHF), does not provide evidence that the TVT-R complies with Quality Management System (QMS) requirements for the design of a medical device.

2. My review of the Ethicon Technical File from the year 2000 confirmed that design controls were not consistently implemented and in fact "a design input document and related risk assessment did not exist."[2] In particular, required design documentation, including but not limited to design requirements, design verification and risk management were not conducted and/or are not available to demonstrate that the acquired system functioned as designed and in a safe manner. This is a deviation from well-recognized standards that apply to medical devices.

3. Ethicon has not complied with International Standards and industry norms which require risk management to be conducted and updated throughout the lifecycle of the medical device. Ethicon did not ensure that a design risk assessment was conducted for the TVT-R prior to marketing the system to ensure that it was safe for its intended use. Ethicon performed two quality system audits of Medscand and found deficiencies; however, the deficiencies were not fully corrected.

4. Ethicon failed to use available customer feedback, complaint data, and the advice of their own Medical Safety Director to routinely update the risk analysis to make design and/or process improvements. This violates both Ethicon procedures and industry standards. More importantly, failure to comply can and did jeopardize the health of end users (patients). In 2002, Ethicon identified eleven (11) new potential hazards that were not included in the application failure mode and effect analysis (aFMEA) originally prepared by Medscand.[3] Although seven (7) of the eleven (11) newly identified hazards had been considered by Ethicon, Germany, in a retrospective design failure mode and effect analysis (dFMEA), Ethicon personnel responsible

[2] Eth.Mesh.22136776.
[3] Eth.Mesh.01317508.

for complaint analysis and post market activities were not aware of these findings, and therefore failed to properly analyze and evaluate these hazards throughout the lifetime of the device.

5. In 2006, Ethicon introduced LCM to the market. Ethicon leveraged existing MCM data to support the launch of LCM despite the fact Ethicon had prior knowledge that patient safety can be compromised by a change in the material properties of a device. One of these changes was increased stiffness of the LCM (LCM is stiffer than MCM). Ethicon was aware that the stiffer LCM could lead to painful patient complications, but these risks were not adequately assessed in the risk assessment process. Leveraging data in this fashion violates the applicable standards. Instead, a medical device company must consider new complications that may arise from a change in the material properties and those complications must be reported, analyzed and acted upon by Ethicon.

6. The QMS at Ethicon related to design control, risk management and post-market feedback were broken. Design specifications and risk analyses were not conducted until five to seven years after the TVT-R was first marketed. The remediation efforts to generate the missing documentation were ineffective at capturing and evaluating design related risks, did not foresee new risks, or incorporate risks that were known or should have been known to the team charged with design control. Additionally, the risks were not updated and mitigated upon post-market feedback to prevent recurring failures, making the activities more of an effort to fulfill a requirement than to provide a safe product. When a manufacturer does not adhere to proper design process standards, the manufacturer cannot ensure that its products work as intended and are safe for their intended use and this deviates from the standards that apply to the manufacturer, in this case Ethicon.

## IV. RELEVANT STANDARDS FOR MEDICAL DEVICE MANUFACTURERS

### A. RELEVANT INTERNATIONAL STANDARDS GOVERNING QUALITY MANAGEMENT SYSTEMS

There have been QMS standards applied to many industries prior to the development and implementation of industry specific standards. One of the first standards used was MIL-Q-9858A Quality Program Requirements which was issued April 9, 1959. MIL-Q-9858A was an input to the ISO 9000 series of standards, Quality systems: Specifications for design/development, production, installation and servicing, which were originally implemented in 1987. It is apparent that international standards governing the QMS and associated risk management practices for medical devices pre-date the initial design of the TVT-R which occurred in 1995[4]. These are industry norms which are <u>not optional</u> to implement. My work in this field with medical device companies involves the application and adherence to these standards. There are other standards that apply, including:

1. **<u>ISO 9001-QUALITY SYSTEMS—MODEL FOR QUALITY ASSURANCE IN DESIGN, DEVELOPMENT, PRODUCT, INSTALLATION AND SERVICING AND EN 46001QUALITY SYSTEMS MEDICAL DEVICES-PARTICULAR REQUIREMENTS FOR THE APPLICATION OF 9001</u>**

[4] Eth.Mesh.03932912 ("The History of TVT").

ISO 9001 is a non-industry specific QMS which is utilized either as a stand-alone standard or in conjunction with industry specific requirements such as EN 46001. ISO 9001 defines organizational and management requirements relating to quality processes. ISO 9001:1994 was broken into twenty (20) elements which define organizational/management responsibilities, quality system procedures, contract review as well as design controls, process controls, inspection and test methods. Responsibilities for handling of nonconforming product, complaints and corrective and preventive action (CAPA) are also covered.

In the case of Medscand, design and development was covered under ISO 9001 supplemented by EN 46001.[5] For example ISO 9001:1994 states that design input requirements relating to the product are to be identified, documented and reviewed, whereas EN 46001 adds a requirement for medical devices to "identify requirements that are related to the *safety* of the medical device and shall include such requirements as design input data."[6] In addition to merely identifying and creating a system that complies with these standards (which a medical device audit may recognize), it is also necessary to ensure that those systems actually work as intended, providing the necessary feedback for patient safety and subsequent action as necessary (which a medical device audit in my experience may not catch).

## 2. ISO 13485 – MEDICAL DEVICES--QUALITY MANAGEMENT SYSTEMS—REQUIREMENTS FOR REGULATORY PURPOSES

ISO 13485 is a medical device industry standard relating to QMS which defines documentation requirements, management responsibilities, human resources, design control, product realization, and measurement analysis and improvement. This standard also defines how a medical device manufacturer should handle complaints and product or system related CAPAs once a manufacturer becomes aware of feedback from any source. ISO 13485 has defined the requirements for proper risk analysis in the medical device industry since 1996. The methods for implementation of risk analysis have been deployed using BS EN 1441 and ISO 14971.

## 3. EN 1441- MEDICAL DEVICES—RISK ANALYSIS

Standards which identify and assess risks have been in existence since as early as the 1940s and were refined for specific application to medical devices when design controls became a requirement in the United States on June 7, 1997. EN 1441: 1997 Medical devices—Risk analysis was approved on September 13, 1997 and was the standard in place at the time of TVT was placed onto the European market.[7] This standard required that medical device manufacturers identify and analyze hazards during the design phase of a project to determine the suitability for

[5] SS-EN 46-001 1994-06-23 is the Swedish equivalent standard.
[6] EN 46001:1993 § 4.4.3.
[7] EN 1441: 1997 embodied the concepts of Risk Analysis more specifically defined in the ISO 14971 standards. The safety of the device and hazards associated with use of the device are required to be assessed, analyzed and reduced during the design of a device and reviewed if risks change over time.

use.[8] The standard requires that a medical device manufacturer's risk assessment should include hazards that could arise from the functional failures of a medical device (i.e., after a medical device has been permanently implanted in the body). Furthermore, the characteristics of a medical device are required to be evaluated for their intended use: "previous use of an ingredient or material does not necessarily assure its suitability in similar applications. Account should be taken of the intended use."[9]

Specific questions are to be addressed during the analysis including, but not limited to, the influence of biodegradation on the material, information on the chemistry of the material, and hazards related to the use and reasonably foreseeable misuse of the device and accessories. EN ISO 1441 also requires review of the risk analysis in light of new data as risks change over time.

## 4. ISO 14971 – MEDICAL DEVICES--APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES

ISO 14971 is the primary standard in the medical device industry defining how to perform risk management, and remains the guiding standard today. While ISO 13485 states that risk management is necessary for medical device manufacturers, ISO 14971 sets forth an overview of essential steps to perform risk management as shown in Exhibit 2.

Although the concepts of risk management were embodied in the BS EN 1441 standard, ISO 14971 specifically calls for: a risk management plan; risk management procedure; and residual risk evaluation and overall residual risk evaluation. A key concept of the standards and their implementation is:

"It is accepted that the concept of risk has two components:

a) the probability occurrence of harm;
b) the consequences of that harm, that is how severe it might be."[10]

As shown below, while analysis of a medical device involves multi-disciplinary input, the analysis of the risk posed by the design embodies crucial and basic concepts of patient safety. Key questions must be asked, documented, resolved and reviewed before a medical device design is deemed complete and in compliance with industry standard. To ignore this crucial process is a violation of the design standards.

The initial step in risk management related to medical device design is risk analysis for a specific device and intended use.[11] For the risk management process to function properly, such that the device's design does not harm people, the team performing the analysis requires "expertise in areas such as:

[8] EN 1441: 1997.
[9] Id.
[10] ISO 14971: 2000: Introduction and ISO 14971: 2007: Introduction.
[11] ISO 14971:2000 Section 3.2 and ISO 14971: 2007 Section 3.1.

- how the medical device is constructed;
- how the medical device works;
- how the medical device is produced;
- how the medical device is actually used;
- how to apply the risk management process."

## B. RISK PLANNING AND USE OF FMEA ANALYSIS

The purpose of risk management is to protect people from physical injury or damage to health. Risk planning is an essential starting point for defining risk management activities. The plan is utilized to identify both the applicable device(s) and associated life cycle phase. The risk management team and their authorities are also to be defined in the plan. Although no specific risk acceptability levels are prescribed, each company is required to responsibly define their criteria for acceptability within the plan and ensure that a process is in place to apply and assess risk control measures. The medical benefit after application of risk control measures must outweigh the residual risk. This is classic risk-benefit analysis. Key to this analysis (the "risk") is actual occurrence of patient harm.

In order to effectively plan and implement risk management activities, a cohesive team must be formed with clear roles, responsibilities and communications. Members from design, manufacturing, quality, and post-production all must fully participate to achieve the desired outcome. As a leader of many risk management efforts, it is my experience that for risk management to successfully identify and evaluate all risks associated with a medical device, it is necessary to have feedback from experts in various fields during the design phase. Additionally, the entire product life cycle must be included in the risk management process. A depiction of the interaction between entities for a functioning design control system is shown in Figure 1 below.

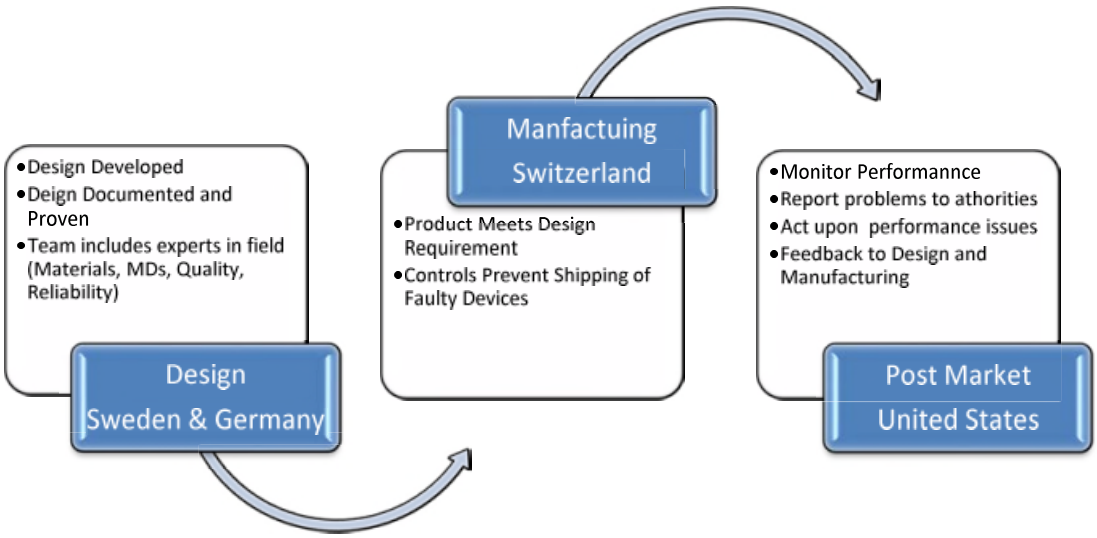


Figure 1: Team Collaboration for Effective Risk Management

There are several tools that may be utilized to implement risk management activities. These include, but are not limited to, fault tree analysis (FTA), failure mode effect analysis (FMEA), and hazard and operability study (HAZOP). In my experience, of all the risk management tools, the FMEA analysis is utilized most frequently for analysis of risk in medical devices.

The FMEA is a technique by which the consequences of an individual fault mode are systematically identified and evaluated.[12] "Failure modes" means the ways, or modes, in which something, such as a medical device, might fail both under intended use and foreseeable misuse conditions.[13] Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual. "Effects analysis" refers to analyzing the consequences of those failures. The FMEA encompasses the identification of the potential causes of failure, an estimate of their severity, the potential frequency, as well as the potential for these failures to be detected. For every risk that is identified, a manufacturer then has a duty to mitigate the risk as far as possible,[14] meaning that they need to reconsider the design of the product so as to eliminate any potential risks to the fullest extent feasible. This is true for all kinds of medical devices. If risk mitigation cannot occur through product design, a manufacturer must attempt to minimize the risk by incorporating protective measures. A protective measure, in the cases of an implant, could be the addition of an accessory to the kit that makes the surgery more precise or reliable such as a guide or tool, or a tool to remove the device in the event of a complication. I have worked with medical device companies that have incorporated such protective measures for implantable devices. The manufacturer may also add a warning about the hazards, and provide training to the product's users. Warnings and training are the least effective means of minimizing risks of a product and should only be used as a last option.

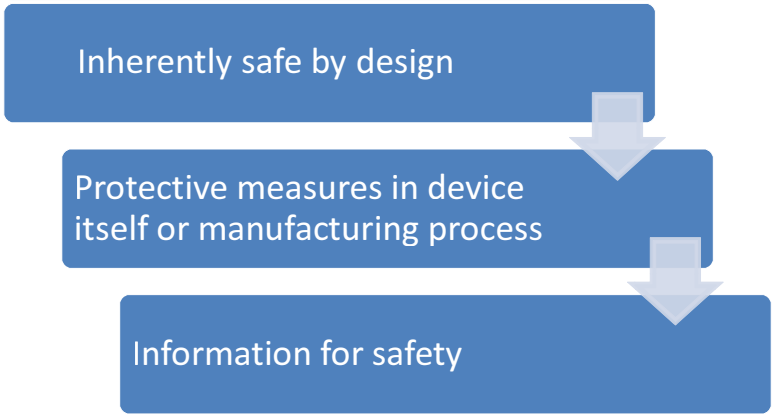


Figure 2: Risk Options[15]

[12] ISO 14971: 2000: Annex F and ISO 14971: 2007: Annex G.
[13] ISO 14971: 2000 Section 4.2 and ISO 14971: 2007 Section 4.2.
[14] ISO 14971: 2000 and ISO 14971: 2007 use the term "as low as reasonably practicable" (ALARP), whereas ISO 14971: 2012 uses the term "as far as possible" (AFAP).
[15] Id.

For an FMEA to work, all potential risks must be identified to ensure that the product's design is as robust as possible. If this is not done, the manufacturer cannot ensure that the device will function as intended and the manufacturer cannot ensure the safety of the device in patients.

Traditionally, there are four (4) different types of FMEAs that can be conducted during the risk assessment phase of product development: (1) System (concept) FMEA; (2) Design FMEA (dFMEA); (3) Process FMEA (pFMEA); and (4) Service FMEA (sFMEA).[16] In my experience, manufacturers of non-active permanently implantable medical devices do not conduct sFMEAs because repair and maintenance activities are not anticipated. Instead, an application FMEA (aFMEA) is often conducted in conjunction with the dFMEA to look at potential failures associated with the use and misuse of the product by the end user.[17]

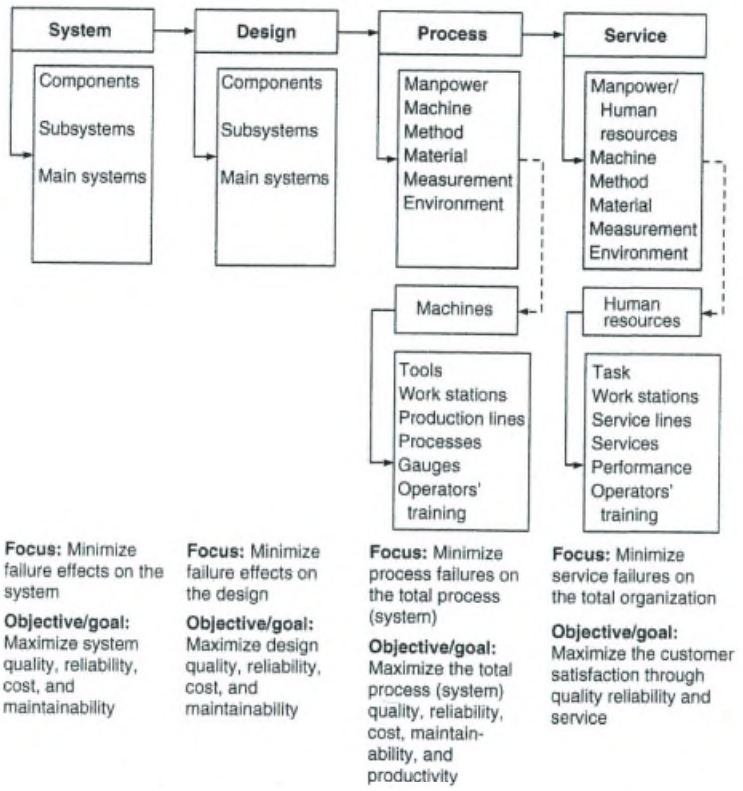


Figure 3: Types of FMEAs[18]

Acknowledging that use of a medical device entails some degree of risk,[19] the dFMEA is conducted during the design phase of product development to ensure any and all product and system related features that could lead to patient harm are identified and designed out of the system to the extent feasible. For product features that could harm a patient, a pFMEA is

[16] Failure Mode and Effect Analysis, FMEA from Theory to Execution, D. H. Stamatis, Second Edition, p.40.
[17] Id.
[18] Failure Mode and Effect Analysis, FMEA from Theory to Execution, D. H. Stamatis, Second Edition, p.41
[19] ISO 14971: 2000 and ISO 14971: 2007 -Medical devices- Application of risk management to medical devices.

conducted on the manufacturing process for a new product, and an aFMEA looks at risks associated with the application or a product (such as surgical implant of the device). An FMEA requires the identification of all potential failure modes for a particular product. For each potential failure mode, an estimate is made for its severity (S), its occurrence rate (O), and its ability to be detected (D).

The "System" FMEA is one of the four (4) types of generally accepted FMEA's. The system FMEA is a predecessor of or may be integrated with the design dFMEA and focuses on failure modes between the system functions (such as the needle, tape and guide) to identify system interactions and deficiencies.[20] System level analyses are critical in that they directly relate to the overall application of the system in its intended use environment rather than only constituent parts. A system level FMEA would consider for example, where a device is inserted, the final placement of the device, instrumentation utilized and instructions for use and/or surgical technique. The goal is to identify the risks associated with the entire system itself when used as intended and with reasonably foreseeable misuse by the medical device manufacturer.[21]

### C. POST-MARKET PRODUCT ASSESSMENT REQUIRES RISK MANAGEMENT PROCESS INPUTS

The FMEA serves as a tool that allows for risk management using process inputs and is to be updated with time and experience. That is why the FMEA is considered a living document that must be updated to take into account any additional risks or failure modes that are identified during both the design phase and during the product's lifecycle. After a device is on the market, information is gathered through multiple sources including product complaints and others as illustrated in Figure 4. As such, medical device manufacturers are also required to vigilantly assess performance after the product is on the market.[22] This requires risk management process inputs, meaning that the product manufacturer must continue to gather information related to its products and then identify the root cause of the product's failure. The manufacturer is in the best position to gauge what information must be collected. In my experience, the manufacturer of an implantable medical device will not only collect and review patient complaints, but will set up systems staffed with the necessary experts to retrieve the explanted device and analyze it for the root cause of failure. These concepts are well-recognized industry standards that can be achieved quickly and efficiently. In fact, I have personally been involved in such efforts with implantable medical devices during the course of my career, which involved notifying physicians and patients and retrieving implantable devices to gather root cause failure data. The standards require this basic vigilance when patient safety is at stake, especially in a permanently implantable device.

If, and when, additional or unanticipated risks are identified, the risks must be added to the original FMEA, and the FMEA must be updated to show how the risk was identified, analyzed, and then mitigated. Identification of new risks requires a medical device manufacturer to analyze and, if appropriate, change the design of its product or system so as to eliminate or minimize the risk to patients. To comply with QMS requirements, complaints and other forms of feedback are to be routinely trended using statistical techniques to identify changes in product or service

[20] Failure Mode and Effect Analysis, D.H. Stamatis, Second Edition, Pg.41.
[21] ISO 14971: 2000 Section 4.2 and ISO 14971: 2007: Section 4.2.
[22] MEDDEV 2.12-1 Guidelines on Medical Device Vigilance System (January 2013).

performance that do not occur by chance (i.e., are statistically significant). This process then repeats on a periodic basis and new failure modes are identified and brought to the attention of Executive Management during Management Review, as required by ISO 13485. In short, this means that Management of the medical device manufacturer must follow up on these identified failure modes to ensure that action is taken, either through device changes, updated labeling or field action.

Additionally, each product change should be reviewed to determine if the change could impact the risk assessment of the product. The review of each change for risk applicability should be documented. If properly deployed, the risk management process will create and maintain a robust product design as it will help ensure that the product that is on the market is safe, performs as intended, and that known or knowable risks will be identified, and warned about or mitigated. Figure 4 illustrates a depiction of the after-market process for ensuring design safety. As shown, numerous inputs are monitored, documented and Executive Management takes corrective action where necessary.

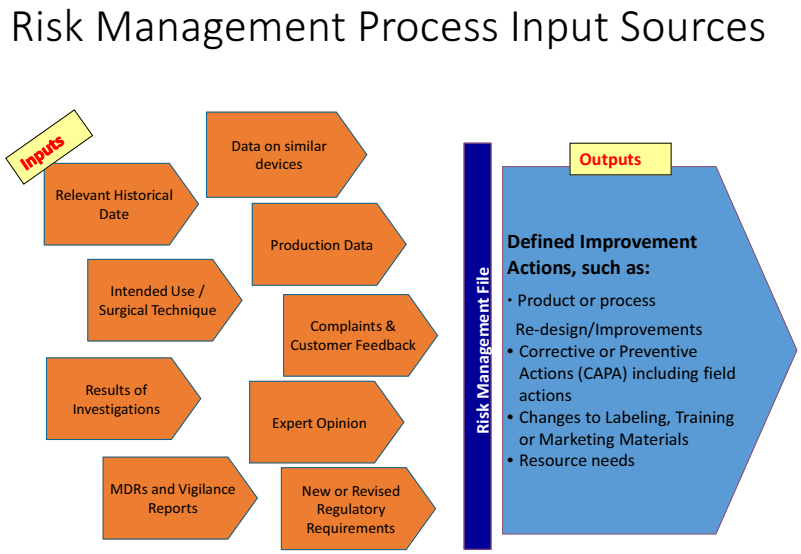


Figure 4: Risk Management Process Input Sources

## D. ETHICON'S OWN INTERNAL STANDARDS REGARDING RISK MANAGEMENT

Ethicon's own internal risk assessment documents and witnesses confirm that the risk management process is as I have described it. Dan Smith, Ethicon's Corporate Representative for the design and development of Ethicon's Stress Urinary Incontinence products, acknowledged

that Ethicon's internal policies are actually written to comply with the international standards.[23] At Ethicon, the Medical Affairs department was tasked with being the final "approver" of the risk management process.[24] Testimony of Ethicon engineers has confirmed that the FMEA process is intended to capture "all of the potential risks to a patient's health or safety.[25] Dan Smith, Ethicon's Corporate Representative for the design and development of Ethicon's SUI products acknowledged that Ethicon's risk management tools are supposed to assess known risks.[26]

Aaron Kirkemo, a past Medical Director at Ethicon, testified that once risks are identified, "you will go ahead and if it is an unanticipated event…you need to go back and try to figure out…mitigation strategies."[27] Ethicon employees have also acknowledged that the FMEA "analysis for each product" "should be documented thoroughly within the company."[28] Moreover, Ethicon Regulatory Affairs Manager Bryan Lisa has acknowledged that it is possible that if a risk can't be designed out or is too severe to just warn about, is it possible that the device may not be sold.[29] Testimony of Ethicon employees has acknowledged that the dFMEA goes beyond physical properties of the product and also "addressed how the product is going to perform after it's been placed in a body or when it's being placed in a body."[30]

Dan Smith, Ethicon's Corporate Representative for the design and development of Ethicon's SUI products, explained at his deposition that during the design and development of a device, Ethicon used the (Devise Design Safety Assessment (DDSA) mechanism as described in PR602-003 as the primary tool to assess risk.[31] Dan Smith explained that Ethicon subsequently changed their risk management tool to utilize dFMEA, aFMEA, and pFMEA tools and that this was the equivalent process to using the DDSA.[32]

There are three (3) primary Ethicon procedures that govern the requirements for implementation of Risk Management[33]:

1. PR602-003 Procedure for Medical Device Risk Management [34]

This procedure defines the requirements for risk management activities as a systematic part of design risk management. The purpose of this procedure is clearly identified as "[t]his procedure will define the device design risk management system for evaluating device safety" and includes planning, setting risk criteria, identifying hazards, risk assessment, risk reduction and control. This procedure defines that a core team is typically used based on expertise to

[23] Deposition of Dan Smith, June 4, 2013, 669:1-6.
[24] Deposition of Bryan Lisa, December 19, 2011, 52:1-6.
[25] Deposition of Scott Ciarocca, March 29, 2012, 97:23-98:21.
[26] Deposition of Dan Smith, May 16, 408:19-21.
[27] Deposition of Aaron Kirkemo, January 6, 2014, 39:14-40:9.
[28] Deposition of Bryan Lisa, December 19, 2011, 49:9-13.
[29] Deposition of Bryan Lisa, December 19, 2011, 51:8-15.
[30] Deposition of Bryan Lisa, December 19, 2011, 47:18-25.
[31] Deposition of Dan Smith, May 16, 2013, 303:11-304:8.
[32] Id.
[33] Each of these procedures were revised over time; therefore specific requirements associated with each document depends on the exact date in question.
[34] Eth.Mesh.08438584.

conduct risk assessments by means of a series of DDSAs. The procedure calls on the team to determine if all hazards are identified.

A key requirement of this procedure is that the DDSA must be reviewed and updated as new information becomes available. Specifically, the complaint database is to be reviewed and if a "discrepancy exists between the DDSA and Product Complaint database, an investigation into the root cause must be conducted."[35] Potential outcomes include repeating the analysis for the new hazards, educating the user, and changing the device design.

2. OP650-010 Operating Procedure for Device Safety Assessment (DDSA)[36]

This procedure defines how to conduct the DDSA for new or modified products. The DDSA is based upon the questions presented in the risk management standards used to identify system characteristics in its intended use environment that may affect safety[37],[38]. DDSA's are required at three (3) time points in the design cycle: during the concept phase, during product development and a final report. The final design must be approved as safe prior to presentation to the Medical Affairs Director. All reports are to be filed in the DHF. Risk control plans were only required for risks determined to be of such significance risk to require risk reduction.[39]

3. OP650-011 Operating Procedure for Design Failure Modes and Effects Analysis (dFMEA)[40]

This procedure provides step-by-step instructions for conducting a dFMEA as a risk reduction technique for risks estimated to be controlled per the DDSA. At Ethicon, each of these rankings is on a scale of 1-10. A Risk Priority Number (RPN) is assigned by multiplying the rankings for severity, occurrence, and detection. Therefore, a RPN is between 1 and 1000. In accordance with OP650-011 where an RPN exceeds two hundred ninety four (294), a risk reduction must occur. A Recommended Action Plan is required to evaluate the potential cause and effect.[41] During review of the risk management procedures, I found no rationale for selection of the RPN cutoff of 294 and therefore the relationship to an actual risk benefit decision remains unclear.

## V. ETHICON DID NOT FOLLOW INDUSTRY STANDARDS AND ITS OWN SOP WHEN IT DEVELOPED AND MARKETED THE TVT-R

I have reviewed Ethicon documents relevant to its FMEAs and its Risk Management Processes. My review establishes that Ethicon did not comply with Industry Standards or its own internal standards when designing the TVT-R and similarly did not utilize or implement appropriate post-marketing standards to ensure that known product failure modes were addressed

[35] Id.
[36] Eth.Mesh.10618465.
[37] EN 1441:1997 Section 3.2.
[38] ISO 13485:2001 Annex A.
[39] Eth.Mesh.10618501.
[40] OP 650-011, Version 1. Version 1 of OP650-011 does not contain a Bates Number. There are multiple versions of this Operating Procedure.. Revision Six (6), Eth.Mesh.03742864, was a "substantial re-write," which added the Application FMEA procedure.
[41] Eth.Mesh.09893522.

throughout the life cycle of the product. This failure to appropriately design this product in conformity with well-established industry standards failed to protect the ultimate user of this product—patients—from potential complications and failures that can affect their health and welfare.

### A. AUDITS DO NOT GUARANTEE COMPLIANCE WITH QMS REQUIREMENTS

Ethicon relied on the results of audits conducted at Medscand to determine compliance with QMS requirements. I reviewed an audit report from a routine ISO 9001/ 46001 audit conducted by Ethicon in accordance with a J&J corporate checklist.[42] The audit was also follow up to a 1996 audit conducted of Medscand by Ethicon. Although only a brief summary of findings was available, the initial audit showed that nonconformances were found relating to the device specification, design history file, document control, and complaint handling. The 1998 follow-up audit also revealed nine new nonconformances. No documentation of actions taken to correct the issues was located.

Audit nonconformances may indicate that systems are not in place, which is important to know. But more importantly, medical device companies and those that conduct audits of them (like I do) understand that there are limitations to any audit. For example, an audit only reveals a sample of information available from records and observation of processes taking place during the audit. Since the audit only represents a point in time, it is not a predictor of future performance. In my experience as an auditor I have seen companies holding both ISO 9001 and ISO 13485 certifications, that clearly do not adhere to standard practices or industry requirements. In one case, a certification audit was conducted while the entire facility was closed, thus the auditor did not observe any processes or look at current records, and still received their certification renewal. I audited the facility shortly thereafter and observed that inspections were not being performed, processes were not documented, equipment was not routinely calibrated and test methods not qualified.

However, a series of thorough due diligence audits and a complete review of their Quality Systems over time should have revealed a more balanced picture of overall adherence to quality management system and operational practices. Thus, Ethicon was aware or should have been aware either before it purchased the TVT or shortly after that key design control and risk information was missing. It wasn't until an internal audit of the Risk Management Process was conducted on November 23, 2010 that continuous problems associated with the risk management process were highlighted. The audit report documented a major finding that agrees with the conclusion documented in this report; the risk assessment process was not conducted in accordance with procedures which were based on industry standards.[43]

### B. PROBLEMS WITH ETHICON'S TVT-R DESIGN CONTROL AND RISK MANAGEMENT PROCESSES

[42] Eth.Mesh.01317611.
[43] Eth.Mesh. 02252269.

It is Executive Management's responsibility to "review the suitability of the risk management process at planned intervals to ensure continuing suitability and effectiveness of the risk management process" as part of the company's overall QMS.[44]

Ethicon's first SUI sling was the Gynecare Tension-Free Vaginal Tape System manufactured for Ethicon by Medscand. Ethicon entered into an agreement on February 14, 1997, with Medscand to produce TVT-R devices for them.[45] The original TVT-R devices utilized mesh produced by Ethicon in Scotland. Subsequent to manufacture of the device, the mesh/needle subsystem was returned to Ethicon for kitting and sterilization. In September of 2000, the manufacturing facility changed from Medscand in Sweden to Ethicon in Switzerland. Design control activities were transferred to Ethicon in Germany.

1. The TVT-R MCM Design History File

I reviewed the Design History File (DHF) for the TVT Retropubic mechanically cut device. Dan Smith, Ethicon's Corporate Representative for the design and development of the TVT family of products agreed that the two "factbooks" contained in Eth.Mesh.01316727-Eth.Mesh.01316765 and Eth.Mesh.01317508-Eth.Mesh.01317613, make up the entire design history file for the TVT base product.[46] I found the TVT-R DHF to be lacking critical documentation regarding the TVT-R system design and associated processes. For example, no design requirement documents, design review or design verification records or dFMEA were within the DHF, which are all required. Additionally only one (1) risk related document was located, which was an aFMEA. Moreover, Dan Smith further testified at his 30(b)(6) deposition that as Ethicon's Corporate Designee on the design and development of the TVT family of products, Ethicon doesn't have any DDSA in its possession prior to the time that the product was sold to women in the USA.[47] The dFMEA is of utmost importance because it is the primary tool used to make sure the design of the entire system working together using the intended surgical method does not present hazards that will lead to harming people. If the hazards are not properly identified and prioritized in the design phase, they cannot be mitigated through a change to the design of the system or by adding protective measures in the device or labeling.

2. Design History File Remediation

In 2000, Ethicon took over manufacturing of the TVT-R device from Medscand and transferred design control activities to Ethicon GmbH (Germany). A review of the Medscand technical documentation confirmed that design controls were not consistently implemented and in fact "a design input document and related risk assessment did not exist."[48] Additionally, "Ethicon Germany as the designated design control location undertook DHF remediation by generating the missing documents, to both fulfill requirements and prevent future problems related to change control."[49] These new documents were created between 2000 and 2002—

[44] ISO 14971:2000: Section 3.3 and ISO 14971: 2007: Section 3.2.
[45] Eth.Mesh.03932912; Eth.Mesh.09746948.
[46] Deposition of Dan Smith, June 4, 2013, 729:1-4 ("Q. So Exhibit 266 and 267 make up the entire design history file for the TVT base product. Correct? A: That is my understanding.").
[47] Deposition of Dan Smith, June 4, 2013, 650:13-651:3.
[48] Eth.Mesh.22136776.
[49] Id.

approximately five year after the TVT-R was designed and three years after the TVT-R had been released for sale into the European and US markets. The series of documents also served as the basis of the change in mesh color from clear to blue and a change to sterile disposable instrument packaging. Documents included generation of design inputs and outputs (clear), a dFMEA design inputs/outputs (blue), a DDSA for packaging and design review documents. Design verification and process validations were also undertaken.

The retrospective dFMEA created by Ethicon GmbH is not credible in my opinion due to the following characteristics:

- Neither industry practice nor internal procedures were utilized to perform the analyses.
- Severity and probability risk classes are not systematically applied where each "fault mode are systematically identified and evaluated"[50] nor are mitigation efforts weighted commensurate with risk.
- Information conflicts with design requirements, manufacturing processes or post-market data (e.g. "Not imaginable" or no imaginable source of the hazard). This often indicates a lack of communication between groups and/or lack of appropriate experts.
- Omission of known hazards e.g. degradation.
- Decreasing the risk class from *high*, with no mitigation efforts required, to a risk *low* or *impossible*.
- No safety measures appear to have been added and exceptionally, all risks were found to be acceptable. No hazards resulted in a risk priority number/class that required any action which in my experience is very rare.

Several examples of problems associated with the performance and interactions within the retrospective dFMEA efforts are shown in Table 1: 2001 dFMEA Deficiencies.

[50] EN 1441:1997 Medical devices- Risk analysis, Annex D.

| Example Type | Hazard | Severity/Frequency | Contrary Evidence | ETH. MESH | Comment |
|---|---|---|---|---|---|
| "Not imaginable" | Wrong Mesh composition | Not imaginable | MS 729-00 V 32 IR Spectrum for material compared to reference sample | 22136836 | Material specification for Prolene mesh required the material identity to be checked on raw material, therefore the failure was both imagined and a mitigation was put in place yet not on dFMEA. Indicates dFMEA done in a vacuum, incorrect team or to check a box (paperwork exercise) |
| Contradiction | Mesh not cuttable | Not imaginable | Design input / output matrix | 10587965 | The design requirement is "treatment is cuttable" |
| Not based on post market data | Over tensioning of tape | Long Term/Critical Probable | DDSA Re-evaluation Internal Memo | 01317513 | Risks associated with over tensioning of tape such as roping or curling are not defined in the analysis when it is known that over tensioning can lead to and urinary retention dFMEA states urinary retention is caused by the user |
| Not based on post market data | Post-Operative erosion | Long Term/ Critical | Mechanical Properties of urological implant materials | Mesh stiffness | Stiffer mesh is more likely to deform, fray, and loose particles when subjected to the forces the mesh is expected to encounter both during and after implantation The clear mesh was shown to be stiffer than the blue mesh, however the clear mesh accepted for continued use based upon input of one surgeon, Dr. Ulstem and continued to be marketed. |
| | | Occasional | Shepard.pdf | | |
| Omission | Mesh degradation | Not Evaluated | DDSA Re-evaluation | 6661877 | Mesh broken and torn mesh are not evaluated. Complaint trending reveals both as "new hazards" |
| Failure to perform its function | Removal due to failure | Long Term/ Critical | Customer Complaints | Deposition of David Robinson, July 24, 2013, 181:12-18 ("So, physicians within the | dFMEA states removal would not generate other hazards, however a revision surgery is a serious hazard. |

| | | | | | |
|---|---|---|---|---|---|
| | | | | United States it looks like from these complaints were having difficulty inserting or difficulty removing the device, at least the physicians who were making these complaints.? A. Well, there were complaints of such, yes.”). | |

Table 1: 2001 dFMEA Deficiencies

3. Design Control Failures

Ethicon, Germany focused initially on review of device performance due to a significant number of complaints for mesh to needle detachment [51] which lead to a product recall in September and October 2000. The cause of the defect was twofold:

1) "The attachment process of mesh to needle had been out of control with respect to the position of the shrink tube on the needle." A change to the specification to define the correct position for the shrink tube and the addition of a 100% inspection were implemented to improve the problem.
2) The test originally intended to verify that design and manufacturing failures were detected was not effective. "The original test method for attachment was not capable to identify defective product."[52] Furthermore the test had in place for needle push/pull-off had not been completed or implemented for product released because the relevant requirements had not been defined. Ethicon was not using the test method to detect failures during initial production.

Although design inputs are required and ISO Certifications were in place, design specifications were not adequately captured or implemented, therefore it was evident that an uncontrolled change or drift had occurred. "There was indication that a previous change in the specification of the shrink tube has indirectly caused insufficient attachment."[53] Lack of consistent use of design controls including design specifications and transfer of the design into production with invalid test methods did in fact lead to a defective product reaching the consumer Design control failures could can lead to a loss of or decrease in function in the device, an alternative surgical method and increased surgical time which could lead to serious injury and require a post- market report. The impact of this design control failure was a focus of the 25 April 2002 Design Safety Analysis Re-Evaluation Memo indicated that 1:3000 implants involved reportable complaints related to pull-off.

The fact that specifications were not generated, test methods did not prevent defective devices from being shipped and multiple complaints not leading to immediate corrective actions

[51] Eth.Mesh.10587984.
[52] Id.
[53] Id.

show that the design control feedback loop as shown in Figure 5 is was broken. and ineffective.

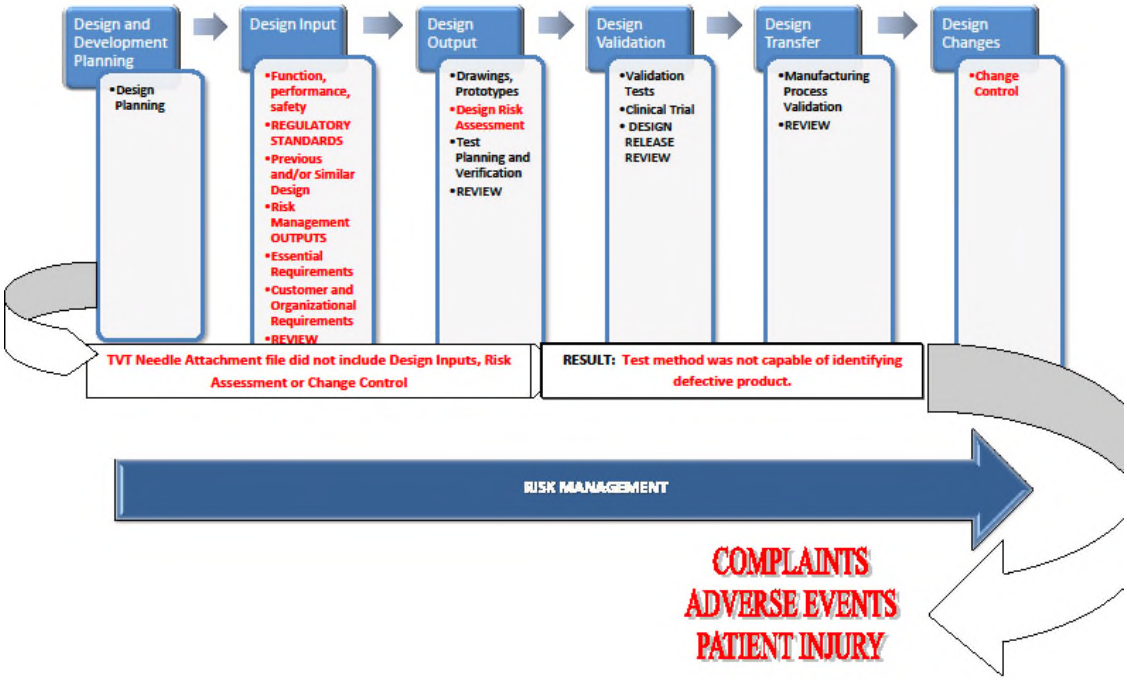


Figure 5: Design Control Elements and Feedback

No new risks were found to be associated with the change from clear mesh to blue mesh,[54] however the stiffness of the clear mesh was found to be significantly greater ($p=0.005$ with $\alpha = 0.05$) that the blue mesh.[55] The 2001 dFMEA determined that no mitigation efforts were called for and all risk associated with stiffness were acceptable. Again upon introduction of LCM in 2006 the laser-cut TVT mesh was measured to be about three times stiffer that the machine cut mesh.[56]

An April 25, 2002 letter titled "Device Design Safety Assessment (DDSA) Re-Evaluation for TVT" noted that "The TVT product was released in Europe in October 1997 and the US in October 1998."[57] The risk assessment (aFMEA) performed by Medscand in July 2000 was used as a reference. Based on this review and analysis of complaints, it is evident that the individual responsible for complaints and post-market assessments had no knowledge of the dFMEA conducted by Ethicon GmbH. Conversely, the complaint data was not used to monitor for new or increasing risks. The feedback loop required for an effective system was not functional.

[54] Eth.Mesh 22136722.
[55] Eth.Mesh 10588140.
[56] Eth.Mesh 01809080.
[57] Eth.Mesh.06661874.

The 2002 review of data included approximately 213,000 TVT-R devices that had been released to the field between October 2000 and March 2002. Complaint data was reviewed as appropriate and it was found that there were eleven (11) potential new hazards which had been left off of the July 2000 Preventia application risk assessment.[58] Had the QMS been functioning properly, the complaint data would be compared to both the aFMEA and dFMEA to ascertain appropriate updates and mitigation actions. The eleven (11) hazards identified by Ethicon at this time, which had not been included in the previous risk assessment were: "Vaginal Extrusion; Erosion/Urethral; Perforation by Mesh; Infection; Vaginal Incision; Urethral Tear; Mesh Broken; Torn Mesh; Bent Needle; Mesh Kinked(Twisted) and Dull Needle."[59] These are all risks that Ethicon knew or should have known about at the time of launch of the TVT-R. Seven (7) of the eleven (11) "new" hazards were not new at all—instead they had previously been identified. It is concerning that these complaints were not known to Ethicon employees. Equally concerning is that the truly new complaints—four (4) out of the eleven (11)—were never addressed throughout the dFMEA process. All potential risks should have been assessed prior to launch, documented, and prevented where possible both during the initial design of the product and continuously after the product is on the market. Again, this was not done even though this was a brand new device which was designed to be permanently implanted in vaginal tissues in women across the United States (and the World). Simply establishing procedures without devoting proper resources or follow-up can, in my significant experience, do more harm than good.

4. 2006 Complaint Review

Ethicon conducted a second complaint review on the TVT-R on 23 Feb 2006 for the date from of Aug 2003 through Jan 2006. [60] The top five (5) complaint categories that accounted for approximately 65% of the complaints were:

a) Mesh Fraying/Roping
b) Sheath Damage
c) Erosion
d) Exposure
e) Pain

There is no evidence that Executive Management took any further action to mitigate or follow up on the root cause analysis of these complaints.[61] Nor is there any evidence that an in-depth root cause failure analysis was performed. Ethicon, as part of the World's largest medical company, had the resources and access to expertise necessary to perform these functions. And in my experience, even small start-up medical device companies can, and often do, call on consultants like me to address risk management and implement corrective actions. It is not the industry norm to wait on others to collect and analyze the risk profile of a medical device that is (1) new to the market (and called "revolutionary" by the company); (2) placed near vital organs; and (3) permanently implanted.

5. Deficiencies with Ethicon's Legacy Risk Assessment

[58] Id..
[59] Id.
[60] Eth.Mesh.02319312.
[61] Eth.Mesh.00167119 (LCM was intended to reduce particulate loss as well as the potential for mesh fraying).

Ethicon conducted other risk assessments during the life of the TVT-R product that were also deficient. Analyses of "Legacy Devices" which included both the TVT and TVT-O devices were conducted in 2007 and 2008 respectively.[62] This was an effort to remediate the risk management files for devices released prior to January 31, 2005 for devices that had not gone through an ISO 14971 risk management process. The TVT-R met the definition and was included in the review process. Executive Management was required to address known hazards, remediate them or change the labeling to address the severity, duration and frequency of the harm. However, this was not done.

The "Legacy" risk remediation effort was fundamentally flawed for the TVT-R based on Ethicon's assumption that products with varied designs (mechanical and laser cut), and varied surgical approaches (retropubic and transobturator) could be grouped together and analyzed as one.[63] Both Industry standards[64] and Ethicon DDSA procedures[65] start by looking at the intended use of the device and how it is to be implanted and placed. Multiple surgical methods cannot be analyzed together in a risk remediation, nor can multiple design types, since each combination of surgical technique and design characteristics yield a distinct risk profile that must be analyzed individually.

Despite this, Ethicon tried to leverage risk management documentation for the TVT MCM device by relying on and incorporating documentation from other Ethicon products with laser cut mesh. For example, the 2010 TVT Technical file combines risk analysis for the original TVT retropubic mechanically cut device along with the TVT-Exact, despite the fact that the TVT Exact is a different device using a different surgical technique that is only offered exclusively with laser cut mesh.[66] These risk management reports for the legacy TVT and TVT-O products include post marketing surveillance data from both laser cut and mechanically cut mesh, without separating out the adverse event rates and risk profile between the two products.[67] Without such an analysis, potential risks could not be properly mitigated through the design process.

Regardless of the fact that the "Legacy" systems were analyzed together, Ethicon still did not address several of the top the eleven (11) known hazards identified in the 2002 complaint analysis or the 2006 complaint analysis. In fact, discussion notes from the team in charge of reviewing complaints for the Legacy Risk Management Report indicate that there is "no associated harm"[68] with many complaints including lower abdominal pain, broken, frayed or kink mesh or vaginal exposure/ extrusion." The resulting Legacy Risk Management Report concludes after review of complaint data that despite the flawed risks analyses, no updates to the aFMEA or dFMEA were required.[69] Additionally, since the residual risk was determined to be "moderate" no risk benefit analysis was required by Ethicon. Also, based on limited information reviewed to date, the risks were not "moderate." Instead, life altering changes are reported, even in internal Ethicon documents. This is a major risk when dealing with permanently implantable devices near vital organs.

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[62] Eth.Mesh.10618726.
[63] Eth.Mesh.10618757.
[64] EN: 1441: 1997, ISO 14971:2000 and ISO 14971:2007.
[65] Eth.Mesh.08438590.
[66] Eth.Mesh.22404550.
[67] Eth.Mesh.10618767;Eth.Mesh.10618794.
[68]Eth.Mesh.10618768.
[69]Eth.Mesh.08438590.

## C. PROBLEMS WITH ETHICON'S COMPLAINT REPORTING

### 1. Ethicon was made Aware of a Patient Complication in 2004 and Ethicon did not Analyze or Report this Complication Until 2014

Ethicon documentation reveals that Ethicon has failed to report TVT complications in violation of Ethicon's own obligations. For example, in a July 20, 2004 email titled "TVT erosion", Olivia Derwin, a Gynecare account manager in Great Britain, writes to Janice Burns, an Ethicon Marketing Manager, regarding a patient who was "1 year and 4 months post TVT with the tape eroding into the bladder."[70] Later the same day, Janice Burns forwarded this email to Axel Arnaud, an Ethicon medical affairs director in France and ultimately a scientific director of Gynecare in Europe.[71] Janice Burns asked Axel Arnaud, "Can you advise me what papers there are that outline treatment of TVT mesh found in the bladder?"[72] The next day, on July 21, 2004, Axel Arnaud responded and identified two articles, which are titled "Postural perineal pain associated with perforation of the lower urinary tract due to insertion of a TVT" (published in the British Journal of Gynecology January 2003) and "Reoperation after complicated TVT procedures" (published in the Journal of Urology in September 2001).[73] Lynn Meyer, Ethicon's Corporate Representative regarding internal analysis and reporting of adverse events, acknowledged that if the articles describe complications with the TVT, those should be reported to the FDA.[74]

Ethicon's corporate representative regarding internal analysis and reporting of adverse events, Lynn Meyer, testified that the TVT complication identified in this email was not identified by Ethicon nor reported to the FDA until nearly ten years later in a June 16, 2014 Ethicon Complaint File Report that was created in response to Lynn Meyer's deposition notice.[75] In fact, the Complaint File Report indicates that "this information was retrieved during the discovery process of a deposition."[76] Lynn Meyer confirmed that this refers to the fact that she read the deposition notice and became aware of this and then didn't find documentation.[77] Lynn Meyer further acknowledged that this complaint information came to Ethicon almost ten years before the complaint file report was created.[78]

### 2. The Complications Following TVT Surgery Described in 2001 and 2003 Publications were not Addressed by Ethicon Until 2014

Lynn Meyer also acknowledged that she has found no indication that the TVT complications described in the articles identified by Axel Arnaud in 2004 had ever been analyzed by Ethicon's Worldwide Customer Quality.[79] Moreover, Lynn Meyer acknowledged that she has found no evidence or documentation that the complications described in these articles had ever been

[70] Eth.Mesh.03910799-Eth.Mesh.03910800.
[71] Deposition of Lynn Meyer, August 20, 2014, 136:2-15.
[72] Id. P.136:11-13.
[73] Id. P. 136:16-137:14
[74] Id. P.138:1-4.
[75] Id. P.138:8-142:21.
[76] Depo.Eth.Mesh.00006387.
[77] Deposition of Lynn Meyer, August 20, 2014, 142:1-14.
[78] Id. at 142:15-21.
[79] Id. at 142:23-143:3.

reported to the FDA by Ethicon.[80] Both of these articles describe complications in patients following TVT surgery.[81] Lynn Meyer testified that a Complaint File Report was created on June 16, 2014 in response to complications described in the 2003 article titled "Postural perineal pain associated with perforation of the lower urinary tract due to insertion of a TVT."[82] Ethicon also created a Complaint File Report on June 16, 2014 in response to complications described in the 2001 article titled "Reoperation after complicated tension-free Vaginal Tape procedures."[83] Both of these Complaint File Reports list the "Alert Date" as "7/21/2004."[84] Moreover, Lynn Meyer acknowledged that once the information known in these articles was known to Ethicon, both Ethicon's procedures and FDA regulations required that the information be analyzed by Ethicon and reported to the FDA.[85]

Ms. Meyer's testimony about Ethicon's failure to act is exactly why audits are not the end of a company's due diligence obligations. Rather, one can have systems, but miss the most critical information The above examples are specific examples of how Ethicon did not comply with Ethicon's own internal requirements regarding complaint reporting and how the quality system feedback loops were broken. Ethicon documentation, including the testimony of Ethicon's Corporate Representative, Lynn Meyer, demonstrates that Ethicon was alerted to patient complications in 2004, but these same complications were not included in Ethicon's complaint database, nor were they provided to the FDA until June 2014, in response to litigation. This information supports my opinions in this case.

## VI. CRITICAL RISKS IGNORED BY ETHICON

The failure to properly adhere to the design process without proper checks and balances jeopardizes patient safety. In this case, the data reviewed demonstrates that Ethicon's QMS does not ensure that the proper design controls and risk management processes have addressed several known risks associated with the TVT device even to this day.[86] Had the QMS's design control and risk management processes been implemented for the device, the risks should have been addressed and therefore minimized. These known risks and/or failure modes include, but are noted limited to:

1) Polypropylene's susceptibility to *in vivo* degradation;
2) Mechanically Cut TVT Mesh's susceptibility to roping, curling, and deforming;

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[80] Id. at 143:4-9.

[81] Wyczolkowski, M. et al. Reoperation After Complicated tension-free Vaginal Tape Procedures. The Journal of Urology. Vol 166: 1004-1005, September 2001; Hilton, P. et al. Postural perineal pain associated with perforation of the lower urinary tract due to insertion of a tension-free vaginal tape. BJOG, Vol 110, P.79-82, January 2003; see Deposition of Lynn Meyer, August 20, 2014, 143:10-146:19; 148:8-149:18.

[82] Deposition of Lynn Meyer, August 20, 2014, 147:6-148:6; Depo.Eth.mesh.00006394.

[83] Deposition of Lynn Meyer, August 20, 2014 151:19-152:11; Depo.Eth.Mesh.00006401.

[84] Depo.Eth.Mesh.00006401.

[85] Deposition to Lynn Meyer, August 20, 2014, 150:25-151:15.

[86] The clinical implications of each of these complaint categories are discussed by medical physicians in other expert reports submitted in this litigation. I offer no opinions on the clinical implications or the frequency of any of those complications throughout the population in this report. Similarly, I offer no opinions on the material properties of the polypropylene mesh used by Ethicon in its TVT-R as those are discussed by other experts for the Plaintiffs in this litigation. Instead, this report deals with whether Ethicon used the knowledge of the complaints it received – both clinical and material / device failures -- to mitigate risks posed by the device design in conformity with Industry Standards and its own SOPs.

3) Mechanically Cut TVT Mesh's susceptibility to fraying and particle loss;
4) The inability to remove the TVT device;
5) Laser Cut TVT Mesh's stiffness.

1. Polypropylene's Susceptibility to *In Vivo* Degradation

Before the eleven (11) new hazards were documented in 2002, which included both broken and torn mesh, it was known both in the industry[87] and within Ethicon that the Prolene® material from which the TVT-R is manufactured degrades over time. A series of internal reports on the outcomes associated with implantation of Prolene® sutures in human and canine explant studies were documented from 1983[88] through 1992.[89] It was shown as early as 1983 that cracking occurred and documentation of these studies revealed that "it is obvious that the severity of cracking is related to the implantation time."[90] Additionally, the studies concluded the polypropylene "appears to be degraded in an oxidative fashion."[91] Furthermore, Ethicon scientist Thomas Barbolt testified that it is Ethicon's position that degradation can occur and this was known by Ethicon as early as 1992.[92] Thomas Barbolt acknowledged Ethicon's internal studies have shown that the Prolene mesh is susceptible to degradation.[93] Moreover, several peer-reviewed published articles have reported that polypropylene material may be susceptible to degradation after implantation in the body.[94]

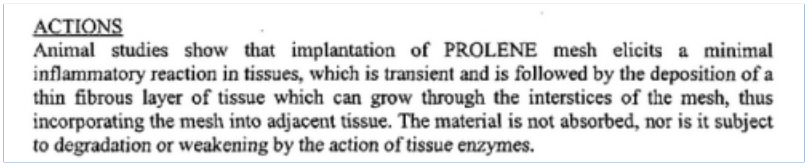
Within the context of Risk Management, it is evident that material degradation was not considered as a hazard which, over time, could lead to mesh embrittlement, cracking and loss of mechanical strength within the patient. In fact, contrary to what was known internally, two (2) issues were allowed to transpire:

a) Analysis of 2002 complaint data revealed broken mesh and torn mesh as new hazards without apparent resultant action. Review of the complaint information in by the 2008 Legacy team[95] shows that complaints associated with broken and torn mesh were discounted as "no associated harm"[96] and no subsequent actions were taken. Review of the Maude database in 2008 Risk Management Legacy Report also revealed multiple cases of vaginal erosion. However, management deemed the need for an aFMEA, dFMEA and pFMEA as "not required for the legacy device."[97] Additionally the "Overall

[87] Eth.Mesh.05845592.
[88] Eth.Mesh.15958410.
[89] Eth.Mesh.12831391; Eth.Mesh.12729337; Eth. Mesh.07690752.
[90] Eth.Mesh.15958412.
[91] Eth.Mesh.12831392.
[92] Deposition of Thomas Barbolt, January 8, 2014, 409:1-13.
[93] Deposition of Thomas Barbolt, January 8, 2014, 516:21-517:4.
[94] *See* Clave et al. *Polypropylene as a Reinforcement in Pelvic Surgery is not Inert: Comparative Analysis of 100 Explants*. Int. Urogynecol. J. 21:261-270 (2010); Wood, A.J., et al. *Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET hernia meshes from an Individual Patient*. J. Mater. Sci. Mater. Med. 24(4): 1113-1122 (2013); Costello, C.R. et al. *Materials Characterization of Explanted Polypropylene Hernia Meshes.* J. Biomed Mater. Res. Part B: Appl. Biomaterials. 83B: 44-49 (2007).
[95] Eth.Mesh.10618768.
[96] Id.
[97] Id.

Residual Risk Assessment"[98] was determined to be "Moderate" justifying that a Risk Benefit Analysis not be performed.

b) The Instructions for Use (IFU) supplied with each device stated that the material is not subject to degradation as shown in Figure 6 below[99] which is directly contrary to what was known[100].



ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

Figure 6: Instructions for Use

In my opinion, prevention of harm or physical injury to the health of people from degradation of the Prolene in the TVT-R was not the focus of risk analysis as it should have been. Unless prevention of hazardous situations is firmly established, the FMEA will turn into an exercise only to meet market requirements rather than ensuring a dynamic process of continual improvement to the product to protect patient safety.

2. Mechanically Cut TVT Mesh's Susceptibility to Roping, Curling, and Deforming

Ethicon documents state that the MCM Prolene® mesh in the TVT is known to "curl" or "rope" when pulling on the fabric in a given direction.[101] In one instance, when the device did not "lay correctly inside the patient" the device had to be entirely removed and replaced by another device. [102] Ethicon documentation shows that the difficulty placing the device flat under the urethra may also lead to reduced surface area under the urethra and increased localized pressure. The localized pressure then increases the potential for retention.[103]

In the 2002 complaint analysis there were twenty-two (22) documented cases of urinary retention and five complaints of "mesh kinked."[104] Although Ethicon indicated that the hazard associated with kinked mesh was to be evaluated, I saw no evidence that any analysis was performed. Instead, by 2006 there were twenty-eight (28) complaints reported for mesh fraying/roping and six (6) for retention.[105] Due to the grouping of complaints it is difficult to discern which complaints were actually due to the product not lying flat. By October 2006, shortly after the TVT-R complaint analysis,[106] a project was underway that would help the device remain flat and reduce the chance for urinary retention.[107] However, the final Risk Management Report (Legacy) showed that curling/ roping that leads to urinary retention was not

[98] Eth.Mesh.10618757.
[99] Eth.Mesh.10618757.
[100] Eth.Mesh.12831392.
[101] Eth.Mesh.02620533.
[102] Eth.Mesh.02620533.
[103] Eth.Mesh.01822361.
[104] Eth.Mesh.01317514.
[105] Eth.Mesh.02319313.
[106] Eth.Mesh.02319312.
[107] Eth.Mesh.01822361.

addressed for the TVT-R device. Thus the completion of the complaint analyses and Risk Management Plans and Reports do not appear to have driven Ethicon to eliminate situations causing patient harm from roping, curling and distortion of the mesh shape.

3. Mechanically Cut TVT Mesh's Susceptibility to Fraying and Particle Loss

a) Ethicon was aware that fraying and particle loss was an issue with the MCM as early as 1998

Fraying is acknowledged to an issue in the design and construction of the MCM TVT-R product.[108] In fact, the initial aFMEA completed in 1998, and apparently reviewed and approved in 2000, mentions that a failure mode is "particles from Prolene mesh falls off into the tissue."[109] This risk analysis for the MCM TVT-R product further notes that the effect of this failure mode is "no effect. Implantable material."[110] A risk assessment included in the TVT Technical File, dated August 5, 2001 does not specifically list fraying or particle loss.[111]

b) Ethicon concluded that the fraying and particle loss associated with the MCM would not have any clinical significance, without performing any testing

In 2001, Dr. Alex Wang, "one of the most experienced TVT users in the world," reported problems with frayed mesh.[112] However, Dr. Martin Weisberg, an Ethicon Medical Director, concluded that the mesh fraying would be unlikely to have any clinical significance. Dr. Weisberg testified that although did not actually know whether frayed mesh leading to particle loss would have clinical implications, he does not recall whether he or anyone else at Ethicon studied the issue.[113] In 2003, Dr. Weisberg reported that there had been a total of 58 complaints of fraying with the TVT since introduction in 2000.[114] Dr. Weisberg noted that when the mesh frays: "[T]he mesh elongates in places, the mesh narrows in places; and small particles of Prolene might break off… and that [s]tretching of the mesh increases the probability of fraying."[115] However, Dr. Weisberg concluded that "since fraying does not affect the safety and efficacy of the TVT device, it has been determined not to pursue any corrective action at this time."[116] Dr. Weisberg concludes that there is no reason to expect the particles to create a safety risk because it is made of the same Prolene® that has been tested as biocompatible in sutures.[117] Dr. Weisberg confirmed during his deposition that no corrective action was taken.[118]

Moreover, Dan Smith, Ethicon's Corporate Representative for the design and development for Ethicon's SUI products, acknowledged at his 30(b)(6) deposition that he is not aware of any studies to determine whether or not the particles that fall off or did fall off the mesh TVT device

[108] Eth.Mesh.00541379.
[109] Eth.Mesh.01317523.
[110] Id.
[111] Eth.Mesh.10587905-Eth.Mesh.10588903.
[112] Eth.Mesh.03905472.
[113] Deposition of Martin Weisberg, May 31, 2013, 469:23-470:16.
[114] Eth.Mesh.00541379.
[115] Id.
[116] Id.
[117] Id.
[118] Deposition of Martin Weisberg, May 31, 2013: 469:23-470:16.

caused any problems or issues from a clinical standpoint.[119] Ethicon's failure to investigate the clinical implications of a known defect, such as the tendency of the mechanically cut TVT mesh to fray and lose particles inside the body violates industry standards and practices and can jeopardize patient safety.

Additionally, the 2002 complaint analysis indicated that thirty-one (31) documented complaints for mesh fraying.[120] However, the severity ranking in both the aFMEA and in the complaints analysis was determined to be a "1" which is defined as "no effect" in the aFMEA and not perceptible or noticeable[121] in the complaint analysis.

Dr. Weisberg's opinion appears to be contrary to clinical reports of small particles released when cutting the mesh "that migrate through the vaginal wall causing pain."[122] There is also an MDR where the frayed edges of the mesh protruded through the vaginal wall[123] causing painful intercourse.[124]

In 2004, Ethicon continued to receive complaints about fraying and particles falling away from the mesh.[125] Dan Smith, the lead engineer for the TVT-O device, noted that the particle loss was further revealed when the mesh became available in a blue color.[126] Dan Smith noted that: "This is not going away anytime soon and competition will have a field day, major damage control offensive needs to start to educate reps and surgeons UPFRONT that they will see BLUE shit and it is OK."[127] A November, 2004 Ethicon email reveals that, one of the "top 3 complaints" included "mesh frayed."[128] Dan Lamont, an Ethicon Quality Engineer who was the Lead Quality Engineer on the LCM product,[129] acknowledged that at this time (November 2004), "so far there is no official corrective action set up in Neuchatel" where the mesh was cut.[130] The same November 2004 Ethicon email noted that "the root cause of this phenomenon are known: the way to cut the mesh (blade cutting). If we change the way to cut the mesh (ultrasonic or laser cutting) it seems we can limit the mesh frayed defect significantly…"[131] In 2003, a published study by Dr. Pariente concluded that "the very high particle shedding for both Sparc (AMS) and TVT (Ethicon) may be of significant long term clinical concern in some quarters."[132] Dr. Pariente's study showed TVT particle loss as high as 8.5%.[133] Dan Lamont admitted that the fraying of the mesh was a "defect" of the mesh.[134]

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[119] Deposition of Dan Smith, June 4, 2013, 664:22-665:10.
[120] Eth.Mesh.01317514.
[121] OP650-011 Version #1, p21.
[122] Eth.Mesh.05644164.
[123] Eth.Mesh.02620682.
[124] Eth.Mesh.02620914.
[125] Eth.Mesh.00863391.
[126] Id.
[127] Id.
[128] Eth.Mesh.01813975; see Deposition of Dan Lamont, September 11, 2013, 10:16-11:21.
[129] Deposition of Dan Lamont, September 11, 2013, 30:18-24.
[130] Deposition of Dan Lamont, September 11, 2013, 11:22-12:2; Eth.Mesh.01813975.
[131] Deposition of Dan Lamont, September 11, 2013, 12:18-13:21; Eth.Mesh.01813975.
[132] Eth.Mesh.01221055.
[133] Id.
[134] Deposition of Dan Lamont, September 11, 2013, 15:16-16:10.

In 2006, an Ethicon Engineer, Gene Kammerer, made a presentation which showed that the MCM (used in the TVT and TVT-O) have been shown to rope, curl and deform when under tension.[135] Gene Kammerer's presentation showed particle loss, fraying, degradation, roping, and deformation when the MCM was stretched, compared to LCM.[136]

Mesh fraying and particle loss was handled in a similar manner as roping and curling from a risk management point of view. The final Risk Management Report (Legacy) showed that mesh fraying was noted as "no associated harm" by the risk team and not addressed for the TVT-R device. The critical and required actions to address the increased in severity resulting from particle release was omitted. Although additional complaints are noted after implementation of the blue Prolene®, from the risk management documents it appears the team continued to handle the complaints as primarily a "cosmetic" issue rather than a hazard causing significant patient harm. Furthermore, documents from August 17, 1998[137] acknowledge that the release of small fibers from the knitted structure was identified as a product characteristic to be improved when re-designing the future mesh products, however the TVT-R product was not intended to be part of the mesh improvement. To my knowledge and based on my review of Ethicon documentation, this harm to patients was not properly mitigated.

4. Difficulty of Removing the TVT Device

It is not known whether the removal of the device was considered as part of the 1995 initial design of the TVT-R, since the initial design requirements are not part of the DHF (TVT Factbook). By 2001, when the design control and risk management deficiencies were remediated, no safety measures were defined or implemented to address removal of the device. Without the documentation the design intent and considerations are not known. The justification provided was that the patient consented to surgery and removal was a "general risk for invasive procedures; Risk accepted by patient."[138]

The apparent result, which did not appear in the original TVT IFU, is a warning stating "Prolene Mesh is a permanent implant that integrates into the tissue. In cases in which the Prolene Mesh needs to be removed in part or whole, significant dissection may be required."[139]

There are a number of reasons a permanent implant may need to be removed or replaced. The device could fail to perform its intended function or result in one or more of the harmful situations defined in section VI("Critical Risks Ignored by Ethicon"). Additionally there could be other medical complications that necessitate removal of the device in full or in part.

Ethicon's former Medical Director Piet Hinoul has acknowledged that "once the TVT is incorporated into the body, if a complication is resulting from the TVT's presence within the body" it "can be very difficult to treat at times because of the fact that it's permanently incorporated into the tissue."[140] Piet Hinoul further testified that "removal of the mesh, because

[135] Eth.Mesh.08334244; Eth.Mesh.08334245.
[136] Id.
[137] Eth.Mesh.09264945.
[138] Eth. Mesh 10587938.
[139] May, 2015 TVT IFU.
[140] Deposition of Piet Hinoul, January 13, 2014, 807:3-18 (Q. –once it's been incorporated into the body, you can't simply adjust it. You'd have to actually cut into it and move—and remove part of the tape, correct? A. Sometimes

you get tissue ingrowth, can prove to be a challenge."[141] Ethicon Medical Director David Robinson also acknowledged that physicians have had difficulty removing the TVT device.[142]

Nevertheless, the May, 2015 IFU for the TVT device reveals that "Prolene Mesh is a permanent implant that integrates into the tissue. In cases in which the Prolene Mesh needs to be removed in part or whole, significant dissection may be required."[143] Despite this, it appears no steps were taken to provide a tool or redesign (e.g., a different mesh property) that would allow for easier removal of the device. In addition, if removal surgery could do more harm than good, then this additional risk needed to be taken into account. The presence of the mesh creates more harm than good. The inability to remove the mesh may create more harm than good. If so, these additional risks must be taken into account by Ethicon.

5. Laser Cut TVT Mesh's Stiffness May Lead to Patient Complications

a) Ethicon continued to sell the MCM after LCM was on the market

In the fourth quarter of 2006, Ethicon began offering LCM in addition to the existing MCM.[144] Ethicon announced that this change would affect both the TVT-R and TVT-O product lines.[145] Ethicon announced that this change was made to "gain efficiencies in manufacturing processes" while also noting that laser cutting would "reduce particulate loss as well as the potential for mesh fraying."[146] According to an April 18, 2006 Clinical Expert Report for the Laser Cut Mesh "on average, the mechanically Cut mesh lost approximately twice the number of particles as the Laser Cut mesh."[147]

Both Ethicon's MCM and LCM have problems associated with them and neither of them is a better product than the other. Despite Ethicon's knowledge of problems with the MCM, Ethicon continued to market MCM devices even after the LCM mesh was launched. According to Dan Lamont, Ethicon's Quality Engineer for the LCM project, Ethicon chose to continue to

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people try to loosen it, but I would just say—I would agree with you, it's not designed to be readjust able post-replacement. Q. Once—I'm sorry. Once the TVT is incorporated into the body, if a complication is resulting from the TVT's presence within the body that can be very difficult to treat at times because of the fact that it's permanently incorporated into the tissue, correct? A. That is correct.") and Deposition of Piet Hinoul, January 13, 2014, 809:11-810:1 (Q.—and then later an infection occurs, there can be difficulty removing the infected mesh, right? A. In that sequence of events, yes. Q. If mesh has been fully integrated and then an erosion occurs, it can be difficult to remove the full amount of the mesh that you want to remove. You may be able to get the part that's exposed into the vagina— A. Right. Q. –but when you want to get deeper into the tissue that can be difficult, correct? A. Yes...").

[141] Deposition of Piet Hinoul, June 27, 2013, 578: 15-22 (Q. If a patient has a complication that is chronic pain or pain with sex or another complication and the mesh is removed, can that be very difficult?..A. Yes. Removal of the mesh, because you get tissue ingrowth, can prove to be a challenge.").

[142] Deposition of David Robinson, July 24, 2013, 181:12-18 ("So, physicians within the United States it looks like from these complaints were having difficulty inserting or difficulty removing the device, at least the physicians who were making these complaints.? A. Well, there were complaints of such, yes.").

[143] May, 2015 TVT IFU.

[144] Eth.Mesh.00167119.

[145] Id.

[146] Id.

[147] Eth.Mesh.00167104.

sell the MCM despite knowing that it had the potential for degradation, particles loss, stretching, and roping.[148]

b) LCM is stiffer than MCM

The LCM had substantially different physical properties than the MCM, as the LCM was stiffer. In March 2006, Gene Kammerer presented results regarding elasticity testing of LCM and MCM which showed that LCM was less elastic than MCM: "MCM meshes stretch between 55.8% and 33.4%. The LCM meshes stretch between 39.5% and 32.1%."[149] Additionally, a December 14, 2004 Ethicon memo found that at 1" of stretch, the laser cut TVT was "about three times stiffer than the machine cut TVT mesh."[150] However, Ethicon decided against conducting clinical testing to establish the safety and effectiveness of the devices affected by using the LCM.[151] Relying on the performance of a different product (TVT-R MCM) and assuming the new product or change in manufacturing of the material is safe in not consistent with industry norms.

The risk that changing the way the material is made may change its properties and affect patient safety. For example, the LCM dFMEA notes that if a mesh is too stiff it can cause the following harms: "Harm: Pain, Damage to Urethra, Urethral Impingement, Damage to Bladder."[152] Ethicon documentation has revealed that stiffer meshes may lead to complications in patients.[153] Moreover, published, peer-reviewed clinical literature agrees that stiffer meshes are associated with increased patient complications.[154] Despite Ethicon's knowledge that a mesh that is too stiff can cause painful complications, Ethicon continued to sell this mesh to patients and did not warn of these complications. Ethicon's continued marketing of the LCM TVT mesh violated industry standards and practices and jeopardizes patient safety.

Additional internal documentation on laser cut mesh supports my opinion that it is a deviation from the standards to leverage the performance of old material (MCM) to new material (LCM). Moreover, Ethicon documentation reveals that Professor Carl Gustaf Nilsson, an Ethicon consultant who has published a study on the TVT Retropubic device,[155] has noted that he "[w]ill not use Laser cut mesh."[156] Both Ethicon's LCM and MCM have problems associated with them and neither product is a better product than the other.

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[148] Deposition of Dan Lamont, September 11, 2013, 30:18-24.
[149] Eth.Mesh.00302181.
[150] Eth.Mesh.01809080.
[151] Eth.Mesh.00167104 (April 18, 2006 Clinical Expert Report for Laser Cut Mesh).
[152] Eth.Mesh.01218019 (dFMEA for Laser Cut Mesh); Eth.Mesh.22012565 (Technical File Amendment—Laser Cut Mesh).
[153] Eth.Mesh.02185584; Eth.Mesh.08968369; Eth.Mesh.08969368; Eth.Mesh.04077109; Eth.Mesh.08041930.
[154] *See* Dietz, H.P. et al. *Mechanical Properties of Urogynecologic Implant Materials*. Int. Urogynecol. J. (2003) 14: 239-243; Moalli, P.A., et al. *Tensile Properties of Five Commonly Used Mid-Urethral Slings Relative to the TVT*. Int. Urogynecol. J. DOI 10.1007/s00192-007-0499-1. (2007); Okulu, E. et al. *Use of Three Types of Synthetic Mesh Material in Sling Surgery: A Prospective Randomized Clinical Trial Evaluating Effectiveness and Complications*. Scandanavian J. of Urology. 2013; 47: 217-224.
[155] *See* Nilsson, C.G. et al. *Seventeen Years' Follow-Up of the Tension-free Vaginal Tape Procedure for Female Stress Urinary Incontinence*. Int. Urogynecol. J. DOI 10.1007/s00192-013-2090-2 (2013).
[156] Eth.Mesh.04048515.

## VII. ETHICON MANAGEMENT DID NOT UPDATE THE TVT DEVICE'S WARNING INFORMATION, DESPITE KNOWLEDGE OF PRODUCT COMPLICATIONS

As I have explained above, Ethicon's management had a responsibility to evaluate and assess product complaints regarding the TVT device and then incorporate that information into the design of the device, including the physical design, protective measures and/or changes to the device labeling. There must have been documentation of the response to these complaints. Ethicon documentation and testimony reveals that Ethicon's management were alerted by Meng Chen, Ethicon's Medical Director and Safety Surveillance Director, who testified that she "repeatedly observed" complaints of "dyspareunia" in reports regarding Ethicon's TVT products.[157] Meng Chen acknowledged that "because of the frequency with which" she saw dyspareunia, she "alerted some of [her] superiors at the company and made them aware of that."[158] Ethicon documentation reveals that after reading patient complaints relating to Ethicon's TVT family of products, Meng Chen wrote an email to Ethicon Management, including Mark Yale, the head of Ethicon's Quality Engineering and Risk Management department at that time, in which she stated "[o]ur post-market knowledge with these products are much more than what we have in the IFUs for all three types of TVTs…My reason for bringing this point to you is maybe you may be able to look into it from senior management perspective and to facilitated the IFU updated for all three TVTs, particularly in the area of 'Potential Adverse Reactions.'"[159] Meng Chen testified at her deposition, that since she brought a "medical doctor's perspective" she had a perspective that that senior management may not have.[160] Meng Chen further testified that updating the IFU to a level that reflected the current knowledge of the manufacturers on the potential adverse reactions associated with the TVT products was crucial because this would allow physicians to "conduct a more thorough and more effective preoperative risk-benefit consent."[161] Ethicon management never addressed these issues raised by Meng Chen. Ethicon management's inaction on this issue, as required by the foregoing design standards, fundamentally ignored patient concerns and the safety of this permanently implantable device. As explained in this report, this started from the very beginning of the acquisition of the device, through its early development and after it was released to market. Well-recognized international standards for quality management systems and Ethicon's own internal guidelines were not effectively performed to to put patient safety first by effectively planning for and mitigating risk. That is fundamentally part of a safe and effective design. Unfortunately, neither the design standards nor their internal procedures were followed for the TVT-R system.

## VIII. COMPENSATION

The compensation per hour which I expect to be paid for my review, study, and testimony is as follows: $365.00 per hour for review and study, expert report, deposition and trial testimony time.

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[157] Deposition of Meng Chen, October 29, 2013, 121:13-19.
[158] Deposition of Meng Chen, October 29, 2013, 121:21-25.
[159] Eth.Mesh.04092868; Deposition of Meng Chen, October 29, 2013, 189:13-190:21.
[160] Deposition of Meng Chen, October, 29, 2013, 191:23-192:2.
[161] Deposition of Meng Chen, October, 29, 2013, 201:20-202:10.

## IX. LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN THE LAST FOUR YEARS

Arthrex, Inc & Arthrex Manufacturing Inc. vs Parcus Medical, LLC

Mullins et al. v. Ethicon, Inc.

## X. EXHIBITS:

1) Anne H. Wilson Curriculum Vitae
2) ISO 14971 Flow Chart
3) Facts and Data Considered

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Anne Holland Wilson

Digitally signed by Anne Holland Wilson
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